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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,752	04/19/2001	Victor J. Dzau	50025/003002	2781

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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/25/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/839,752

Applicant(s)

DZAU ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 14 and 16 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11. 6) ☐ Other: \_\_\_\_

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### **DETAILED ACTION**

This office action is in response to an amendment filed 11/27/02. Claims 13-16 are pending in this application.

#### ***Priority***

It is noted that this application appears to claim subject matter disclosed in prior copending Application No. 08/524,206, filed 9/8/1995. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question

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whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

*Response to Amendment*

Objection to the Specification had been withdrawn in light of submission of figures in place of tables 5 and 6.

Rejection of claims 13-16 under nonstatutory double patenting has been withdrawn in light of submission of a timely filed terminal disclaimer.

*Claim Rejections - 35 USC § 102*

(Due to the failure of applicant to claim priority to application number 08/524,206 and application number 08/144,717, the filing date of the instant application is considered 4/19/2001<sup>mm</sup> and the following prior art therefore applies).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mann et al, The Lancet, Volume 354 pp 1493-1498 (October 30, 1999).

Mann et al. teach a method for inhibiting neointimal hyperplasia (proliferative lesion formation in blood vessels) using ex vivo vein graft engineering with E2F decoys in humans

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(methods page 1493). E2F decoys were introduced into the lumen of harvested veins of clinical patients. PNA and c-myc- two measures of E2F activity- were decreased, as were graft occlusions, revisions and critical stenoses (findings page 1493).

Claims 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawauchi et al., Circulation Research, pp 1063-1068 (November 24, 2000).

Kawauchi et al. teach a method for inhibiting intimal hyperplasia (proliferative lesion formation in blood vessels) using ex vivo single intraluminal delivery of E2F decoys in primate and mice models (Materials and Methods, page 1063). Specifically in primate models, neointimal thickening was prevented (abstract).

Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzau et al., PNAS, Volume 93 pp 11421-11425 (October 1996).

Dzau et al. teach a method of introducing E2F decoy molecules into cultured vascular smooth muscle cells and rat carotid arteries in vivo (page 11424, column 1, paragraph 1 and 2). In rat arteries, a neointimal formation was reduced.

Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Morishita et al., PNAS, Volume 92 pp 5855-5859 (June 1995).

Morishita et al. teach a method of introducing E2F decoy molecules into cultured vascular smooth muscle cells (page 5855, column 2, 3<sup>rd</sup> paragraph) and rat carotid arteries in vivo (page 5856, column 2, paragraph 1). In rat arteries, a neointimal formation was prevented (abstract).

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Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Dzau et al. (WO 95/11687).

Dzau et al. teach a method of introducing E2F decoy molecules into cultured vascular smooth muscle cells (page 11, line 3-14) and rat carotid arteries in vivo (page 12, line 30-37). In rat arteries, a neointimal formation was reduced (page 14, line 1-13).

### *Response to Arguments*

Applicants traverse the claim rejections under obviousness double patenting on page 3 of the response filed 11/27/02. The terminal disclaimer filed 11/27/02 renders applicants' arguments directed against the double patenting rejection made against claims 13-16 moot. However, in response to applicants' arguments, it is noted that applicants have analyzed the teachings of Mudryji in isolation. The Mudryji reference is applied in combination with the claims of the 08/524,206 application, said combination of teachings renders the claims obvious.

Claim 13, 14 and 16 are rejected.

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3291.

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

February 24, 2003

DAVID GUZO  
PRIMARY EXAMINER  
